INTERNATIONAL STANDARD

ISO 80601-2-13

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Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 2

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie AMENDEMENT 2







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This document was prepared by ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee SC 1, Breathing attachments and anaesthetic machines and Technical Committee IEC/TC 62, Electrical equipment in medical practice, Subcommittee SC 62 D, Electromedical equipment.



ISO 80601-2-13:2011/Amd.2:2018(E)

Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 2

201.1.3 Collateral standards

Replace the second paragraph with the following:

IEC 60601-1-3:2008, IEC 60601-1-9:2007+AMD1:2013 and IEC 60601-1-11:2010 do not apply.

201.2 Normative references

Delete IEC 60601-1-9:2007, Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design.

201.15 Construction of ME EQUIPMENT

Add the following subclause:

201.15.3.5 Rough handling test

Addition:

For an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually, the speed in c) frame-door-shock shall be reduced from 0,8 m/s to 0,4 m/s.

NASIONAL

201.101.4.2.1 Inlet connector

Replace list item a) by the following text:

a) female non-interchangeable screw-threaded (NIST) connector, or

209 Requirements for environmentally conscious design

Replace the existing text by:

IEC 60601-1-9 does not apply.

1

ISO 80601-2-13:2011/Amd.2:2018(E)

Bibliography

Add:

[16] IEC 60601-1-9, Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral standard: Requirements for environmentally conscious design

Renumber subsequent references.





